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The Childhood Vaccination Schedule. Overview and Analysis

Part 1 of 26, The First Vaccine: Hepatitis B

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Introduction

As more vaccines are added to the US childhood immunization schedule, it's imperative that there be a broader public discussion about the prominence of vaccination in public health policy as well as a forthright assessment of the benefits conveyed and the risks involved.

Though vaccines are viewed as vital to the short-term and long-term health of children, asking exploratory questions, debating pros and cons, and engaging in a comprehensive analysis of vaccines are conversations considered off-limits by the mainstream medical establishment.

In the conventional narrative, it is accepted as an article of faith that vaccines are miraculous discoveries responsible for disease eradication and are the most important medical product for disease prevention.

Indeed, today's pediatricians treat the promotion and implementation of the childhood immunization program as their primary duty.

It is widely believed that if we stopped—or even reduced the number of—vaccinations of children, we would be reverting to the Dark Ages. Any individual who challenges vaccine orthodoxy is regarded as a heretic.

Yet, despite this deeply ingrained belief system, a growing number of parents and health advocates are beginning to openly address concerns that have been swept under the rug for years:

- Are all of these required vaccines and doses really necessary?
- Are all of the vaccines safe?
- Are the diseases that the vaccines are designed to prevent truly diseases of concern?
- When scrutinized, does the claim that vaccines are responsible for reductions in disease, disability, and death from a variety of infectious diseases fit with the facts?
- Why has there been such a marked increase in the number of vaccines added to the childhood schedule?
- Has this escalating vaccine program produced an accompanying improvement in health outcomes?
- What happens if a child doesn't receive all of the scheduled vaccines?
- What happens to a child who receives no vaccines—and remains unvaccinated throughout childhood?

Parents need to be able to freely ask these questions and more. And they deserve transparent, fact-based, comprehensive answers.

The information we will present in this series is publicly available. Yet it is not permitted a place in the public discourse. Instead, the pharmaceutical and biotechnology manufacturers of vaccines, the medical profession, the regulatory bodies, and a compromised media apparatus have conspired to create a mystique around vaccines and to persuade the public that vaccines are the holiest of all medicinal products.

To counteract this institutional programming, we are embarking upon a series of articles that will take a close look at each and every one of the vaccines on the childhood schedule and the diseases they are designed to prevent.

Part 1 begins with an overview of the US Childhood Immunization Schedule. Then it takes an in-depth look at the initial shot given to infants on the first day of life—the hepatitis B vaccine.

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The United States Childhood Immunization Schedule: An Overview

In the past few decades, the childhood vaccine schedule in the United States has exploded into what is now the most aggressive vaccination schedule in the world. It wasn't always this way. Most Americans who are today's "baby boomers" likely had only two or three vaccinations—polio, smallpox and DTP—and never more than one shot—one dose of a single vaccine—per visit.

With the recent addition of the Covid-19 vaccines to the childhood schedule, the number of recommended injections between day one and the age of eighteen has ballooned to 72 injections of 90 antigens. Though this regimen constitutes the full immunization schedule in 2023, it will soon be outdone by even more doses of more antigens, if history is any guide.

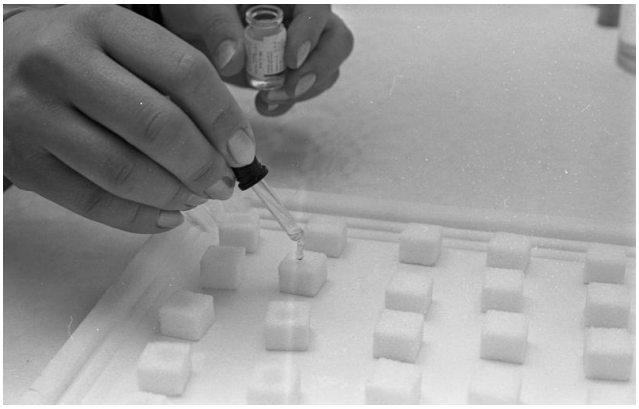
To understand how this veritable cocktail came into being, we need to know the history of how we got here.

The first vaccine mandate in the United States was enacted in Massachusetts in 1810. It was

meant to ward off smallpox. The legislation behind it was essentially an ad hoc law that gave local health boards the authority to require vaccination.

The first public school mandate was issued in Massachusetts in the 1850s. At that time, just as in 1810, the only vaccine of interest was for smallpox. By the end of the 1800s, most of the six New England states had smallpox vaccine requirements for children attending public schools.

Image: Doses of oral polio vaccine are added to sugar cubes for use in a 1967 vaccination campaign in Bonn, West Germany (Licensed under CC BY-SA 3.0 de)



The next significant stride in vaccine recommendations and requirements for children would arrive a century later—in 1954, to be exact, when attention was focused on the polio vaccine developed by Jonas Salk.

By 1955, the polio vaccine was fully licensed. Through the Polio Vaccine Assistance Act, Congress appropriated funds to provide federal grants to states to purchase the vaccine and to defray the cost of planning and conducting vaccination programs.

This Act would become the template for using federal funds to cover various costs of vaccine programs in all the states. Not surprisingly, it also provided the impetus for a mass inoculation campaign for polio.

At this time, there were no codified mechanisms to mandate vaccine uptake. Doctors' recommendations were considered just that—simply guidance, with no strict obligation or enforcement powers.

The 1962 Vaccine Assistance Act established a permanent mechanism to provide ongoing financial support to state and local health departments. This Act permitted the US Centers for Disease Control and Prevention (CDC) to appropriate federal funds for the provision of vaccines and established an advisory group to assist in managing vaccination programs.

To this day, the 1962 Act remains one of the most important mechanisms for aligning local and state health department immunization activities with federal funds to deliver vaccines to children.

In 1964, the Advisory Committee on Immunization Practices (ACIP) was created under the US Public Health Service. Its mission was to review the science and efficacy of vaccines given to children and to make recommendations on when those vaccines should be administered and at what ages.

The 1960s and 1970s saw a wave of new vaccines hit the market. A second type of polio vaccine was developed, as was the first hepatitis B vaccine. The measles vaccine started out as a single vaccine but then was combined with the mumps and rubella vaccines to create the MMR vaccine.

Paralleling the increase in the volume of vaccines in the US was the creation of global immunization programs. In 1974, the Geneva-based World Health Organization (WHO) established the Expanded Programme on Immunization, which was designed to "strengthen vaccine programmes, supply, and delivery, and ensure universal access to all relevant vaccines for all populations across the life course."

These changes radically altered the business landscape of vaccine manufacturing. What was once a cottage industry of small pharmaceutical companies, individual researchers, and physician-scientists evolved into the mega-corporations that exist today.

By 1977, the US government had set up the Childhood Immunization Initiative. Its purpose was to increase childhood vaccination rates and immunize against seven diseases (diphtheria, measles, mumps, pertussis, poliomyelitis, rubella, tetanus) for which vaccines had been developed. Thus began the process by which all 50 states would adopt mandatory school vaccinations.

In the 1980s, vaccines against the hepatitis B virus (HBV), haemophilus influenzae type b, and pneumococcal disease were recommended for children at different ages. By 1983, the number of recommended injections had increased to 23 doses of seven vaccines for children between day one and age six.

In 1986, the National Childhood Vaccine Injury Act created a system of passive and active surveillance for cases of adverse reactions to vaccines as well as a mechanism to compensate any persons injured by vaccines.

With the passage of the 1986 Act and its implementation in 1988, a liability shield for vaccine-makers was created. On the heels of the 1986 Act, the number of vaccines placed on the CDC schedule began to escalate dramatically.

As the list of available vaccines grew, local and state health boards had differing opinions on when to give vaccines, on which children should get them, and on how many vaccines should be given.

In order to standardize vaccine uptake, the first "harmonized" childhood immunization schedule was issued in 1995 by the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP). This single schedule combined the recommendations of all three national groups.

The initial schedule included diphtheria, tetanus, pertussis, measles, mumps, rubella, polio (oral), haemophilus influenzae type b (Hib), and hepatitis B (HepB) vaccines. (The DTP is a combination vaccine for diphtheria, tetanus, pertussis. The MMR is a combination vaccine for measles, mumps, rubella.)

Since then, the schedule has been adjusted whenever a new vaccine is developed or whenever an old vaccine is taken off the market or whenever the risk profile for children changes.

Today, according to the National Conference of State Legislatures (NCSL), all 50 states have legislation requiring specific vaccines for students. Medical, religious, and philosophical exemptions from vaccines vary from state to state, as laws are added or altered by state legislators.

These laws apply not only to children attending public schools but also to those attending private schools and day care facilities.

Currently, 45 states and Washington, D.C., grant religious exemptions to parents who have religious objections to immunizations, and 15 states allow for philosophical exemptions.

As of 2021, five states (California, Connecticut, Maine, New York, and West Virginia) no longer allow religious or philosophical exemptions from vaccination requirements.

School immunization laws in all 50 states grant exemptions for medical reasons.

NCSL literature makes the point that the laws and regulations on vaccine requirements in all 50 states and DC follow the vaccine schedule set forth by CDC.

It's hard to keep track of the upward trajectory of the childhood vaccine schedule. Suffice it to say that in pre-pandemic 2019, the full CDC schedule called for 54 injections of 72 antigens between birth and the age of eighteen. And, not surprisingly, now Covid vaccines have been placed on the child immunization schedule.

This dizzying array of injections begins on a child's first day of life with the hepatitis B (HepB) vaccine.

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The Disease Hepatitis B: A Case Study in Manufacturing Public Perception

The first question every new parent who seeks information on childhood vaccines should ask is, "Does my child really need a vaccine for hepatitis B—and especially on the first day of life?"

Given the low risk of newborns acquiring the HepB infection and the ease with which pregnant mothers can be screened, it's fair to ask why the HepB vaccine is recommended for newborns.

Before arriving at that answer, let's look at how the disease called hepatitis B (HBV) was transformed from a relatively obscure condition that impacted a limited population into a perceived widespread public health predicament.

The conventional characterization of hepatitis B is as a type of viral hepatitis that causes acute and chronic liver infection. It is generally accepted that the requirement for contracting this disease is direct contact with infected blood or other body fluids. These are transmission routes that by any standard pose little to no risk to infants.

That description is how public health officials characterized the disease when the hepatitis B vaccine (HepB) initially gained approval in 1981. Back then and still today, the CDC's own Fact Sheet on the disease hepatitis B does *not* include "all newborns" as a risk group!

Here is the list of hepatitis B risk groups: “injection drug users, homosexual men, sexually active heterosexuals, infant/children of immigrants from disease-endemic areas, sexual/household contacts of infected persons, infants born to infected mothers, health care workers and hemodialysis patients.”

What was it that changed the CDC’s 1982 vaccine recommendation, which targeted *only* the small, “at-risk” population exposed to hepatitis B, into a set of more aggressive policies that would result in the 1991 recommendation that *all* infants get three doses of HBV between birth and 18 months of age?

Furthermore, how did the HepB vaccine become compulsory for all school children in 47 states by the year 2000? This recommendation was issued despite the CDC’s admission of lack of proof that HBV is transmitted in a school setting.

The answer to this anomaly lies in how the public’s perception of hepatitis B has been radically altered through orchestrated media messaging and deliberately provocative depictions of the disease by industry and public health officials.

Notably, the change in the image of the *disease* came immediately after the development, licensure, and 1981 introduction of the *vaccine*.

In the late 1970s, *prior to the approval* of the vaccine, hepatitis B was a disease that had little to no relevance to most Americans and was nowhere to be found on the media radar. Indeed, before the HepB vaccine was developed and marketed, most Americans had little reason to view the disease as a threat to their health or to the health of their children.

New cases of hepatitis B were quite low in the 1970s. They began to rise in the 1980s, concurrent with the AIDS crisis, then began to fall again in the 1990s.

By its own admission, the CDC attributed the 1990s decline to “reduction of transmission among men who have sex with men and injection drug users, as a result of HIV prevention efforts.”

Throughout the 1980s and 1990s, hepatitis B acquired an even more public image. The advent of the AIDS crisis in the early 1980s, the development of genetically engineered pharmaceuticals in the late 1980s, and the political push for health reform in the early 1990s all led to changes in how hepatitis B was presented to Americans.

The media, medical and scientific community all contributed to altering the image of hepatitis B throughout that period.

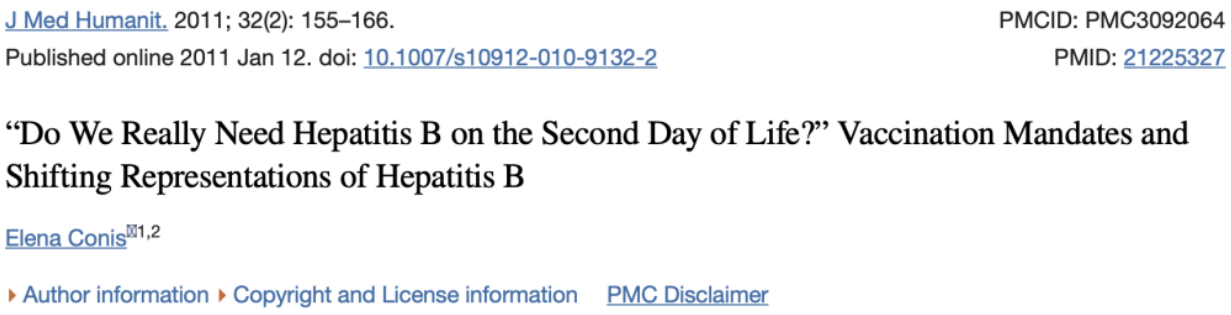
Media outlets would often conflate the hepatitis B virus (HBV) with HIV/AIDS in order to arouse public interest in this once-obscure disease and induce fear of it. Provocative headlines and stories began to surface with claims that hepatitis B was similar to HIV and possibly worse.

The historical medical view of hepatitis B as a disease impacting only a narrow subset of the population was gradually replaced by hysterical media representations that *anyone* could be at risk of it.

In an article, “Do We Really Need Hepatitis B on the Second Day of Life? Vaccination Mandates and Shifting Representations of Hepatitis B,” history of health sciences professor

Elena Conis chronicles some of this history:

> Outlets from the Philadelphia Tribune to Good Housekeeping reported that a third of people with the disease were not in any of the known risk groups. Redbook warned readers that hepatitis was "spreading fast," and the Boston Globe noted that hepatitis was spread by sharing gum, food, toothbrushes, and razors and by body piercing. New York magazine, in a feature titled, "The Other Plague," recounted the stories of a young woman who contracted a fatal case by getting her ears pierced, a young man who was infected when mugged at knife-point, and a woman infected at a nail salon. Frequent mention of the prevalence of asymptomatic carriers heightened the sense of an immediate health threat: in the words of the New York magazine reporter, anyone could be one of the U.S.'s 1.5 million "Typhoid Marys," unwittingly transmitting hepatitis B to people unaware of their risk.



J Med Humanit. 2011; 32(2): 155–166. PMCID: PMC3092064
Published online 2011 Jan 12. doi: 10.1007/s10912-010-9132-2 PMID: 21225327

"Do We Really Need Hepatitis B on the Second Day of Life?" Vaccination Mandates and Shifting Representations of Hepatitis B

Elena Conis[1,2]

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Screenshot of the NCBI article

Such media reports citing hepatitis B disease statistics normally originated with statements made by officials at the CDC.

Most of the inflated disease statistics were generated in the very same ACIP Morbidity and Mortality Weekly Report (MMWR) that called for mass vaccination with the hepatitis B (HepB) vaccine.

In that report, the CDC stated that there are an "estimated 1 million–1.25 million persons with chronic hepatitis B infection in the United States," that "each year approximately 4,000–5,000 of these persons die from chronic liver disease," and that "an estimated 200,000–300,000 new [hepatitis B] infections occurred annually during the period 1980–1991."

To generate those statistics, the CDC, in a move at best considered duplicitous, circled back on itself, citing an MMWR 1990 report as the basis for its claims. Nowhere in either report were scientific references used to support those claims.

Despite the media campaign, uptake for the HepB vaccine was not rising to desired levels. Vaccination of high-risk adults was proving to be difficult, to put it mildly. Their hesitation led to a more systematic strategy at the national level.

In September 1991, the Advisory Committee on Immunization Practices (ACIP) developed and codified a national program for the HepB vaccine: Hepatitis B Virus: A Comprehensive Strategy for Eliminating Transmission in the United States Through Universal Childhood

Vaccination.

In 1992, the WHO followed suit, recommending that "all infants should receive their first dose of hepatitis B vaccine as soon as possible after birth, preferably within 24 hours, even in countries where hepatitis B virus is of low endemicity."

Acknowledging children were not in the at-risk group for the disease, the ACIP committee lamented that "HBV transmission cannot be prevented through vaccinating only the groups at high risk of infection." [Emphasis added.]

Using this rationale, ACIP declared a blanket vaccination policy for all newborns—"a comprehensive strategy to prevent HBV infection, acute hepatitis B, and the sequelae of HBV infection in the United States."

Interestingly, a CDC official admitted in a June 11, 1991, *Boston Globe* article titled, "U.S. To Urge All Children Be Vaccinated for Hepatitis B": "We do not feel that targeting adults for vaccination has worked. This will be the first time that a vaccine is recommended for children to prevent a disease that primarily occurs in adults."

Michael Belkin, the father of a five-week-old baby who died 15 hours after receiving a hepatitis B booster, summed up the situation in his testimony before Congress:

> So in the CDC and ACIP's own words, almost every newborn US baby is now greeted on its entry into the world by a vaccine injection against a sexually transmitted disease for which the baby is not at risk—because they couldn't get the junkies, prostitutes, homosexuals and promiscuous heterosexuals to take the vaccine.

Bluntly put, the CDC effectuated a comprehensive, compulsory hepatitis B vaccine program for every child in the US simply because the initial target population of drug addicts and homosexuals was not keen to accept the shot.

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The Hepatitis B Vaccine Clinical Trials: The Devil's in the Details

It is a near-certainty that few physicians, when presented with a vaccine under clinical trial, bother to study the fine print found on its package insert. Rarely will a pediatrician or any other physician initiate a conversation with a patient or parent about what those trials entailed or what ingredients and possible adverse effects the package insert reveals.

Yet the clinical trial is exactly the first place a medical professional should go to get a clear picture of the safety profile for any vaccine.

Image is from India Mart

In 2017, the Informed Consent Action Network (ICAN) received a tip from a supporter that the clinical trials used by the US Food and Drug Administration (FDA) to license the two children's hepatitis B vaccines, Engerix-B and Recombivax HB, had reviewed safety data for only a few days after injection. This information was readily available on the package inserts.

ICAN attorneys were so stunned by this revelation that they assumed the supporter was making false claims. Upon reviewing the package inserts for both vaccines, however, ICAN found the claims to be true.

The package insert for GlaxoSmithKline's Energix-B vaccine, approved in 1989, acknowledges that the subjects were monitored for *only four days* after administration of the vaccine. By any standard, four days of post-injection data is inadequate to assure a product's safety. As noted by ICAN, "[T]he safety review period in a clinical trial for a vaccine given to babies and toddlers should be longer, since autoimmune, neurological, and developmental disorders will often not be diagnosed until after babies are at least a few years old."

A 2019 study authored by researchers at the FDA and Duke University confirmed ICAN's position. They contended that, compared to the licensing time period for adults, "data on drug efficacy and safety in children may require an additional 6 years."

Another troubling facet of GSK's pre-licensure clinical trials is that Engerix-B was administered to 5,071 healthy *adults and children.* Yet nowhere is there a list showing how many of the 13,495 doses of Engerix-B administered in 36 clinical trials were to adults, how many to children, and how many to infants. Without knowing the number of subjects within each age group, the results of these trials are uninterpretable with respect to the risks of vaccinating infants.

While the trials for Energix-B were certainly less than rigorous, the pre-licensure trials for Merck's Recombivax HB vaccine might hold the dubious distinction of being the most unscrupulous and underpowered trials in the annals of the pharmaceutical industry.

In only three clinical studies, 434 doses of RECOMBIVAX HB, 5 mcg, were administered to only 147 healthy infants and children (up to 10 years of age), who were monitored for a mere *five days* after each dose.

Along with the fact that 147 subjects is a grossly insufficient number upon which to base

any determination on vaccine safety, the ages of the trial participants are anybody's guess. How many infants were in the study? Was there even a single newborn in the study?

Additionally, as is the case with virtually all vaccine clinical trials, neither of these two hepatitis B trials used a proper randomized placebo-controlled clinical trial.

Beyond the untrustworthy nature of the composition and execution of these trials there is also the nagging problem with the difference between the noted *outcomes of the clinical trials* versus *the post-marketing experience.*

In the clinical trials, effects are only studied for a few days immediately following vaccination (with no true placebo), and only minor adverse reactions such as irritability, fever, diarrhea, fatigue/weakness and injection-site pain are mentioned.

But in the "post-marketing data," which means post-approval injections in the general population, a laundry list of more serious adverse reactions such as Guillain-Barré syndrome, multiple sclerosis, encephalitis, thrombocytopenia, meningitis, Stevens-Johnson syndrome, tachycardia and many more are reported.

This is one of the elemental tricks the pharmaceutical industry uses to conceal the nature and extent of injuries that may be attributable to the shots.

More serious adverse reactions are swept under the rug by asserting that "no causal link has been established" between the injection and these reactions.

In the trials, subjects are observed for *only a few days* and nothing is ever found to cause concern.

But when the general public starts reporting real-world, serious adverse events, these are dismissed, and no long-term studies are done that could establish a causal relationship between the shot and the adverse-events reporting.

In a nine-hour deposition, ICAN lead attorney Aaron Siri brought these many problems to the attention of Stanley Plotkin, the "Godfather of Vaccines" who authored what is considered the bible on vaccines.

In the deposition, Siri got Plotkin to admit that the hepatitis B vaccine (given to babies on their first day of life) has not had an adequate safety study:

- Aaron Siri: "How long does it say that safety was monitored after each dose?"
- Dr. Stanley Plotkin: "Five days."
- Siri: "Is that long enough to detect an autoimmune issue that arises after five days?"
- Plotkin: "No."
- Siri: "Was there any control group in this trial?"
- Dr. Plotkin, who had just argued that control groups are essential to gauge cause and effect, answered, "It does not mention any control group, no."

Based on the weight of that testimony, ICAN is currently petitioning the FDA to withdraw the licensure of the hepatitis B vaccines and asserting that they should never have been approved.

Given that the utility of the Hep B vaccine for toddlers is unsubstantiated and that the clinical trials are at best problematic, it would seem incumbent upon the manufacturers to at least provide ironclad evidence for the safety of these products.

So, do they provide ironclad evidence of safety?

The data reveal otherwise.

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Dangers of the Hepatitis B Vaccine: An Open Secret

In the first months of life, a child's brain and biological systems are at critical stages of development. Throughout pregnancy, parents are typically bombarded with directives from their physician, who warns them that a multitude of vaccinations will be essential to protect their child from the impending torrent of infectious diseases.

In addition to the medical stipulations given by their pediatrician, parents are made to understand that they will be faced with mandates for daycare and schooling as well as ever-present societal pressures. The combination of these forces creates a climate of fear and coercion intended to bring about automatic compliance with the childhood immunization schedule.

Little to no information about vaccines is volunteered during most pediatric visits. Parents are expected to obediently trust their physician and place their faith in a medical system that assiduously claims vaccinations are necessary, safe, and effective. Questions challenging the utility and safety of a vaccine are typically discouraged and dismissed.

In the United States, the journey into this world of mass vaccination begins on the day of birth with the hepatitis B vaccine.

To the extent that hepatitis B is a danger to anyone, that risk is understood to be through sexual contact or sharing needles. A sexually transmitted risk or a needle-exchange risk means there is virtually no chance of hepatitis B infection for infants, which calls into question the fundamental rationale for this vaccine.

Less than one percent of all hepatitis B cases occur in children under 15 years old. In North America, Europe, and Australia, a mere one-tenth of one percent are said to be carriers. Of adults infected, 90–95% clear the virus on their own, without intervention.

While it is thought that infants born to mothers who are infected with hepatitis B carry a greater risk of contracting the disease, pregnant women can easily be screened and found positive or negative.

Given the low risk of hepatitis B infection for infants and young children, we have to ask, "Is this vaccine worth the potential risk of neurodevelopmental disorders or other adverse impacts associated with this vaccine?"

The answer to that question can be found by first answering the most important question for any medical product: *Is it safe?*

From the earliest days of development and production, safety concerns have dogged the

various iterations of the hepatitis B vaccine.

Image: This media was obtained from the Smithsonian Institution.

The original version, Heptavax B, manufactured by Merck Sharp & Dolme and approved by the FDA in 1981, was unlike previous vaccines in that it contained inactivated virus collected from plasma of HepB-infected donors rather than live, weakened virus or killed, denatured virus.

Prolific vaccinologist Maurice Hilleman hypothesized that he could make a HepB vaccine by injecting patients with hepatitis B surface protein using three treatments of blood serum, together with rigorous filtration. To obtain the necessary plasma, Hilleman collected blood from gay men and intravenous drug users—groups said to be at risk for viral hepatitis.

Hilleman believed that after vaccination, the body's immune system would recognize the surface proteins as foreign and manufacture specific antibodies that would destroy these proteins. His theory was that if, post-vaccination, the patient were infected with HBV, the immune system would produce protective antibodies that would destroy the viruses.

On November 16, 1981, CBS Evening News reporter Dan Rather touted Hilleman's vaccine as the "first completely new viral vaccine in ten years" and hailed it as "the first vaccine ever licensed in the United States that is made directly from human blood."

Though lauded as a revolutionary medical achievement at the time, the original plasma-derived HepB vaccinewas not intended for widespread use in the US. For one thing, liver cancer was still relatively uncommon in the US. For another, the cost of the vaccine was regarded as prohibitive.

Excitement surrounding this novel plasma vaccine soon dissipated due to a public relations problem. It came to light that the clinical trials that tested the vaccine in the 1970s had included *only* gay men who had been identified as being at high risk of the infection.

The approval of the serum-derived vaccine coincided with the AIDS crisis, which heightened concerns over the safety of using potentially contaminated human serum in vaccines for fear of transmitting live HBV or other blood-borne pathogens.

Specifically, since gay men and injection drug users were frequent blood donors for the vaccine, the concern was that blood plasma could be infected and the vaccine itself could become a carrier for HIV/AIDS.

Unease over potential contamination with human viruses led to the 1986 introduction of a second hepatitis B vaccine, Recombivax-HB. This new type of vaccine, known as a recombinant vaccine, was the first vaccine produced using recombinant DNA technology. Like Heptavax B, Recombivax-HB was manufactured by Merck Sharp & Dolme.

The creation of this new type of vaccine entailed inserting the gene of the HepB virus protein envelope into yeast cells, eliminating the risk of viral contamination from using human serum to produce the vaccine.

Frank E. Young, FDA Commissioner at the time, heralded this development as yet another medical marvel, declaring, "This vaccine opens up a whole new era of vaccine production. These techniques should be able to be extended to any virus or parasite to produce other vaccines that normally cannot be propagated in the laboratory."

Noting that the plasma-derived vaccine, HeptavaxB, had annual sales of only $45 million, Edward E. Penhoet, president of Merck's collaborator, Chiron Corp., suggested that the new Recombivax-HB vaccine would be more profitable for Merck, considering that genetically engineered vaccines are "cheaper to produce" than those derived from human blood.

By 1989, a second recombinant hepatitis B vaccine, Engerix-B, manufactured by SmithKline Beecham, was approved for use in the US.

While the new HepB vaccines were tempering the anxiety that surrounded the previous plasma-based vaccines, a different set of problems materialized in the manufacturing processes and with certain ingredients in the HepB recombinant vaccines.

A 2005 French study titled "Multiple sclerosis and hepatitis B vaccination: Adding the credibility of molecular biology to an unusual level of clinical and epidemiological evidence" highlighted issues with HepB virus polymerase contamination. It asserted:

> We reviewed evidence showing that hepatitis B vaccine HBV has a marked potential to induce auto-immune hazards, neurological as well as non-neurological. We emphasized that for a drug used as a prevention, HBV was remarkable by the unusual *frequency, severity* and *variety* of its hazards.

The study's authors concluded that:

> 'the principle of precaution' should urgently be applied [with] regard to the tiny benefit (if any) of large HepB vaccination in low-endemic countries. In addition, the benefit/ratio of this costly prophylaxis should be seriously re-assessed even in countries where the frequency of HepB is higher.

Another issue cropped up—namely, the genetically modified yeast proteins used in the HepB vaccines. Links between all yeast-containing vaccines and autoimmune disease were

observed, creating concern that this ingredient in the HepB vaccines might cause children allergic to yeast to have a severe reaction to the vaccine.

Indeed, bioinformatics and epidemiological evidence connects the yeast protein found in the hepatitis B vaccines to numerous autoimmune disorders. Yet, according to the French study, "Vaccine makers have refused to perform such checks, resulting in devastating consequences."

On its website, the Hepatitis B Foundation warns, "The vaccine may not be recommended for those with documented yeast allergies or a history of an adverse reaction to the vaccine."

Meanwhile, the CDC's Pinkbook on hepatitis B identified another potential problem: "Some presentations [meaning packaging] of HepB vaccines contain latex, which may cause allergic reactions."

Given that the first dose of the HepB vaccine is recommended—and usually administered—on the day of birth, how is it possible to know if a newborn has an allergy to yeast or to latex or to any of the vaccine's other ingredients?

Yeast and latex allergies are certainly not insignificant concerns. But even more alarming safety concerns have been identified with still other ingredients found in the HepB vaccine.

Until the early 2000s, the original gene-based HepB vaccines, Recombivax and Engerix, contained the mercury preservative thimerosal. Thimerosal is a mercury – and thiosalicylate-containing organic compound with antiseptic, bactericidal, and fungicidal properties. Certain exposures to thimerosal are known to be toxic to the central nervous system, kidneys, liver, spleen, and bone marrow. Some believe that even the tiniest amounts of methylmercury, which is found in thimerosal, carry a risk of adverse neuropsychological outcomes.

A 2016 longitudinal study of the relationship between thimerosal-containing hepatitis B vaccination and developmental delays made this assessment:

> During the decade in which Thimerosal-HepB Vaccines (T-HBVs) were routinely recommended and administered to US infants (1991–2001), an estimated 0.5 – 1 million additional US children were diagnosed with specific delays in development as a consequence of 25 µg or 37.5 µg organic Hg from T-HBVs administered within the first 6 months of life.
>
> [. . .] [This] study provides compelling new evidence to confirm and extend previous epidemiological studies finding a significant relationship between organic Hg exposure from Thimerosal-containing childhood vaccines and the subsequent increased risk of a diagnosis for specific delays in development.

A 2018 cross-sectional study published in the *International Journal of Environmental Research and Public Health* strongly suggested that the 1990s-era thimerosal-containing HepB vaccine caused considerable harm to children. That study concluded:

> This cross-sectional study provides new evidence consistent with and extends the results from previous epidemiological and biological studies on the adverse effects of Hg exposure from Thimerosal-containing childhood vaccines. This study supports a

> significant about nine-fold increase in the risk of adverse effects as measured by receipt of special education services among boys receiving infant Thimerosal-containing hepatitis B vaccination.

The 2018 study added to the chorus of voices demanding that thimerosal be removed from all vaccines given to pregnant women and children.

It is not as though concerns about mercury had not already been raised by regulators. The Food and Drug Administration (FDA) Modernization Act of 1997 called for the FDA to review and assess the risk of all mercury-containing food and drugs.

In 1999, the FDA determined:

> [U]nder the recommended childhood immunization schedule, infants might be exposed to cumulative doses of ethylmercury that exceed some federal safety guidelines established for ingestion of methylmercury, another form of organic mercury (Ball et al., 2001). In July 1999, the American Academy of Pediatrics (AAP) and the U.S. Public Health Service (PHS) issued a joint statement recommending the removal of thimerosal from vaccines as soon as possible.

The FDA statement recommended "a temporary suspension of the birth dose of hepatitis B vaccine for children born to low-risk mothers until a thimerosal-free alternative became available."

Merck responded immediately by making a new HepB vaccine. The company gained FDA approval for its thimerosal-free Recombivax HB vaccine on August 27, 1999. Distribution of the new product began in September.

SmithKline Beecham reformulated its thimerosal-free Engerix-B, which the FDA approved in 2000.

The director of the Institute for Vaccine Safety, Neal Halsey, M.D., assured the public that SmithKline Beecham's new Engerix-B contained only trace amounts of thimerosal (<1 mcg), which, he said, will "have no clinically relevant effects[,] making it equivalent to a thimerosal-free product."

Meanwhile, the CDC recommends that newborns and infants up to the age of six months avoid vaccinations with thimerosal. But it still allows infants over the age of six months to receive the thimerosal-containing HepB vaccines.

Even as thimerosal was being phased out of children's vaccines, safety concerns surrounding yet another ingredient in the HepB vaccine persisted. Disturbing reports relating to aluminum adjuvants found in the vaccines were emerging. They continue to this day.

In a 2008 article in *Mothering* magazine, pediatrician Robert Sears sounded the alarm about the dangers of vaccinations which contained aluminum adjuvants.

Before writing this article, Dr. Sears had embarked on his own inquiry to see if anyone had actually tested and scientifically assessed "safe" levels of injected aluminum. During his investigation, he had discovered an FDA document on aluminum toxicity, which warned:

> Aluminum may reach toxic levels with prolonged parenteral administration [i.e., injected into the body] if kidney function is impaired. Research indicates that patients with impaired kidney function, including premature neonates [i.e., babies], who received parenteral levels of aluminum at greater than 4 to 5 micrograms per kilogram of body weight per day, accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading [i.e., toxic buildup in certain body tissues] may occur at even lower rates of administration.

Another document on the subject of aluminum toxicity, this one produced by the American Society for Parenteral and Enteral Nutrition (ASPEN), emphasized a daily limit of 4 to 5 mcg of aluminum per kilogram (2.2 lbs) of body weight for babies being fed an IV solution containing aluminum.

While neither of these documents mentioned vaccines specifically, both the FDA and ASPEN were of the opinion that all injectable solutions for children should be limited to a maximum amount of 25 mcg of aluminum within a 24-hour period.

The FDA's Code of Federal Regulations explicity states, "The aluminum content of large volume parenteral (LVP) drug products used in total parenteral nutrition (TPN) therapy must not exceed 25 micrograms per liter ([micro]g/L)."

The unsettling fact about the HepB vaccine with regard to aluminum is that each dose—given at birth, at 2 months, and at 6 months—is laced with 250 mcg of aluminum, an amount *far* exceeding the recommended safe levels for large volume parenteral (LVP) drug products.

In a 2011 study, two Canadian scientists, Professor Christopher Shaw and Dr. Lucija Tomljenovic, asked a serious question in the title of an article they co-wrote, "Aluminum Vaccine Adjuvants: Are they Safe?"

The answers they discovered are worth quoting at length:

> Aluminum is an experimentally demonstrated neurotoxin and the most commonly used vaccine adjuvant. Despite almost 90 years of widespread use of aluminum adjuvants, medical science's understanding about their mechanisms of action is still remarkably poor.
>
> Experimental research, however, clearly shows that aluminum adjuvants have a potential to induce serious immunological disorders in humans. In particular, aluminum in adjuvant form carries a risk for autoimmunity, long-term brain inflammation and associated neurological complications and may thus have profound and widespread adverse health consequences. [Emphasis added.] [. . .]
>
> Given that multiple aluminum-adjuvanted vaccines are often given to very young children (i.e., 2 to 6 months of age), in a single day at individual vaccination sessions, concerns for potential impacts of total adjuvant-derived aluminum body burden may be significant. These issues warrant serious consideration since, to the best of our knowledge, no adequate studies have been conducted to assess the safety of simultaneous administration of different vaccines to young children." [Emphasis added.]

Two years later, in 2013, the same scientists produced another study—this one with a statement of fact rather than a question in its title: "Aluminum in the Central Nervous

System: Toxicity in Humans and Animals, Vaccine Adjuvants, and Autoimmunity.“

In this study, Shaw and Tomljenovic concluded:

> In young children, a highly significant correlation exists between the number of pediatric aluminum-adjuvanted vaccines administered and the rate of autism spectrum disorders. Many of the features of aluminum-induced neurotoxicity may arise, in part, from autoimmune reactions, as part of the autoimmune/inflammatory induced by adjuvants (ASIA) syndrome.

No article on aluminum in vaccines is complete unless it mentions UK chemist Christopher Exley, who is a professor of bioinorganic chemistry and group leader of the Bioinorganic Chemistry Laboratory at Keele University. Known as “Mr. Aluminum,” Dr. Exley has devoted much of his life to studying the dangers of aluminum. His particular focus is on the use of aluminum adjuvants in childhood vaccines.

Credited with conducting numerous studies on the subject, Exley is particularly recognized for his discoverythat cells known to populate a vaccine injection site actually take up the aluminum adjuvant from the vaccine into their cell bodies.

Accompanying this finding was his pioneering revelation that antigens and adjuvants are taken up as separate particles.

Both of Exley’s discoveries have implications for the possible role of aluminum adjuvants in instigating serious adverse events *distant* from the vaccine injection site.

Multiple studies have aligned with Exley’s findings that the intramuscularly injected aluminum vaccine adjuvant is absorbed into the systemic circulation and travels to different sites in the body, such as the brain, joints, and the spleen, where it accumulates and is retained for years post-vaccination.

*

Cui Bono?

According to government statistics, the viral disease hepatitis B causes death in fewer than one-quarter of one percent of those who are infected with it. However, it is a near-certainty that even *that* rate is an overestimate, since the death of hepatitis B-infected drug addicts and alcoholics is more likely due to the quantity of drugs and alcohol they imbibe. Those toxic substances, not the disease hepatitis B, are what destroy their liver and other vital organs.

In 1986, five years before the CDC began pushing for vaccination of all newborns, there were fewer than 280 documented cases of hepatitis B infection in children under age 14 in the US. This statistic alone serves as proof that newborns are the least likely human beings on the planet at risk of contracting hepatitis B.

So, given that the vast majority of infants in the US are *not* at risk for hepatitis B and given the copious documentation linking the HepB vaccine to various pathologies (here, here and here), we must return to the question: *Why the fanatical push for universal HepB vaccination for children?*

If we look at the HepB childhood vaccination program from a perspective of health and of "saving lives," we are confronted with a world of contradictions and manipulations—and none of it makes any sense.

But if we look at the HepB childhood vaccination program through the lens of power, money, and control, then everything makes perfect sense.

A 2005 letter written by Dr. Marc Girard to the Director General of the World Health Organization referenced a correspondence he had with an Indian colleague, Dr. J. Puliyel, on the false data being disseminated by the WHO about the epidemiology of hepatitis B in India.

This exchange gives us insight into the processes by which a once-non-existent threat is turned into a public health crisis—and into the ulterior motives underlying this development.

Dr. Girard noted gravely:

> [T]he mechanisms of the deception described by Dr. Puliyel were exactly comparable to those I observed in my own country — and of course with the same results: a plea of "experts" to include hepatitis B vaccination in the national vaccination program, in spite of its costs and its unprecedented toxicity.

He continued:

> It is blatant that in the promotion of the hepatitis B vaccination, the WHO has never been more than a screen for an undue commercial promotion, in particular via the Viral Hepatitis Prevention Board (VHPB), created, sponsored and infiltrated by the manufacturers.

In Sept 1998, while the dreadful hazards of the campaign had been given media coverage in France, the VHPB met a panel of "experts," the reassuring conclusions of which were extensively announced as reflecting the WHO's position: yet some of the participants in this panel had no more "expertise" than that of being employees of the manufacturers.

In the same letter to the WHO, Girard drew attention to a 1997 interview published in the French journal *Sciences et Avenir*, in which SmithKline Beecham's business manager admitted:

> We started increasing the awareness of the European Experts of the World Health Organization (WHO) about Hepatitis B in 1988. From then to 1991, we financed epidemiological studies on the subject to create a scientific consensus about hepatitis being a major public health problem. We were successful because in 1991, WHO published new recommendations about hepatitis B vaccination.

This cynical admission by one of the primary manufacturers of the hepatitis B vaccine offers a glimpse into how the time-honored strategy of problem-reaction-solution is applied in the pharmaceutical industry.

The disease itself is widely seen as superfluous. All that is necessary to produce fear of it—and to greatly profit off of that fear—is to *create the perception* that there is a widespread public health crisis requiring a heroic international medical intervention in the form of a vaccine which, curiously, was already in production leading into the "crisis."

The business manager's confession reinforces the facts surrounding the history of hepatitis B. Importantly, there was virtually no problem with this disease *until after* the vaccine became available. At that point, the disease had to be propagandized for marketing—that is, for bottom-line—purposes.

Tracing the breadcrumbs of the entire production of the hepatitis B vaccine campaign, we detect a pattern: A decidedly non-medical, non-health-related agenda emerges, proving, yet again, that to find the truth, one must always *follow the money.*

For years, vast amounts of financial and political capital have been invested in the hepatitis B vaccine. Enormous amounts of resources have been allocated to its research and development. Each new HepB vaccine has been hailed as a medical wonder.

Despite these monumental efforts, the medical industry did not succeed in persuading its targets to take the vaccine. That failure meant meager returns on enormous investments.

So, to solve this dilemma and address the sunk costs, the pharmaceutical industry, through its cadre of captured policy makers, invented regulations that were fashioned to make the vaccines compulsory for vulnerable infants, whose mothers, recovering from the pains and joys of childbirth, are hardly in a position to give their "informed consent." Thus, a captured customer base is created. And thus, a stream of revenue is guaranteed.

The "at-birth" HepB vaccines have the added benefit, from the manufacturers' perspective, of providing "vaccine training wheels" for new parents, conditioning them to mutely comply with 18 years of routine immunization appointments.

The 12 million doses of HepB vaccine administered to children each year in the US alone—not even counting worldwide—represents a substantial annual income stream for vaccine manufacturers.

The New York Times reported that the average cost to fully vaccinate a child from birth to the age of 18 in a private doctor's office soared from $100 in 1986 to $2,192 by 2014.

And now, in 2023, if a child receives each dose of every vaccine on the childhood schedule in a private pediatrician's office, the cost exceeds $3,000.

In the 21st century, the commercialization of vaccines has expanded into a colossal and profitable global enterprise. According to International Monetary Fund Managing Director Kristalina Georgieva, vaccine policy is now one of the most important drivers of global economic policy.

A Final Word

In two separate congressional hearings in 1999, Michael Belkin, whose infant daughter died of Sudden Infant Death Syndrome (SIDS) within hours of receiving a hepatitis B vaccine dosage, testified, calling the HepB vaccine policy a "bureaucratic vaccination program that is on auto-pilot flying into a mountain" and accusing CDC bureaucrats of "hav[ing] a vested interest in the status quo."

Mr. Belkin's conclusions merit a full recitation of the facts about this deadly vaccine:

- Newborn babies are not at risk of contracting the hepatitis B disease unless their

mother is infected.
- Hepatitis B is primarily a disease of drug addicts, homosexuals, and promiscuous heterosexuals.
- The vaccine is being foisted upon babies because health authorities were unsuccessful in persuading those high-risk groups to submit to this jab. Adverse reactions outnumber cases of the disease in government statistics.
- Nothing is being done to investigate those adverse reactions.
- Those adverse reactions include numerous deaths, convulsions, and arthritic conditions that occur within days of hepatitis B vaccination.
- The CDC is misrepresenting hypothetical, estimated hepatitis B disease statistics as if they were actual cases of the disease.
- The ACIP is recommending new vaccines for premature infants without having scientific studies proving they are safe.
- The US vaccine recommendation process is hopelessly compromised by conflicts of interest with vaccine manufacturers, with the American Academy of Pediatrics, and with the CDC.

We realize that Mr. Belkin was addressing specifically and solely the hepatitis B injection in warning of the vaccine's risk to health. But we would like to close Part 1 by pointing out, on behalf of all children and their parents, the high risk of toxicity and adverse reactions posed by *all vaccines*.

We will be rigorously scrutinizing each and every recommended childhood vaccine in future installments of this series. We hope to provide a framework for a long-overdue assessment of this oft-hidden, off-limits, and highly contentious medical issue.

[The next installment, Part 2 of our 26-part series, will take a look at the rotavirus vaccine.]

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